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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,377	02/26/2002	Catherine Defrenne	BM45379	4141

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	PAPER NUMBER
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/936,377	DEFRENNE ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25, 27, 29, 31, 32, 35, 40, 41, 43, 48-51 and 57-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25,29,31,35,40,41,43,50,51 and 57-59* is/are rejected.

7)☒ Claim(s) *27, 32, 48 and 49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants submission filed on 1/23/07 has been entered. MPEP 7.42.04

Amendment

2. Applicant's amendment filed on10/21/05 is entered. Applicant's arguments filed on 1/23/07 is also acknowledged and entered.

Status of Claims

3. Claims 25, 27, 29, 31, 32, 35, 40, 41, 43, and 48-51 have been amended.

Claims 52-56 have been canceled.

New claims 57-59 have been added.

Claims 25, 27, 29, 31, 32, 35, 40, 41, 43, 48-51 and 57-59 are under examination.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC 112, first paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 25, 29, 31, 35, 40, 41, 43 , 50, 51 and 57-59 are rejected under 35 USC 112, first paragraph, as lacking an adequate written description in the specification.

Claims are drawn to an isolated recombinant polypeptide, an isolated recombinant fusion protein, immunogenic composition comprising an immunogenic fragment of at least 15 or 20 contiguous amino acids of SEQ ID NO:2, wherein the immunogenic fragment is capable, when administered to a subject as a conjugate with a suitable carrier or in a composition which can include an adjuvant, of inducing an antibody response that recognizes the polypeptide SEQ ID NO:2.

The state of the art of epitope identification for the induction of an immune response with linear peptides is as follows: Roitt et al, 1998, Immunology, 4th ed, Mosby, London teach that although it is possible to produce antibodies to almost any part of an antigen, this does not normally happen in an immune response. It is usually found that only a certain areas of the antigen are particularly antigenic, and that a majority of antibodies bind to these regions. These regions are often at exposed areas on the outside of the antigen, particularly where there are loops of polypeptide that lack a rigid tertiary structure (p.7.7-7.8). This is exemplified by the teaching of Holmes (Exp. Opin.Invest. Drugs, 2001, 10(3):511-519) who teaches that rabbits were immunized with synthetic peptides which in each case generated high anti-peptide specific immunoreactivities, however, none of the antibodies exhibited binding to the full length antigen. The author concludes that 'Presumably, expression of these epitopes in the context of the protein

was important and affected the antibody binding ability (p. 513, col 1). Furthermore, this does not take into account the 3 dimensional folding of the native molecule, nor its glycosylation or other post-translational modifications and other characteristics which are of significant importance in an antibody response. Peptides or synthetic antigens cannot effectively substitute for the natural tertiary and quarterary structure of a protein in a physiological situation. Further, there is no teaching in the specification of which part of the protein should be used to produce antibodies which will bind specifically to SEQ ID NO:2

Moreover, as written, the claims encompass claims to defining specific epitopes of SEQ ID NO:2. However, there is no teaching in the specification of whether or not the epitopes are linear or comprise 3-dimensional structures. Herbert et al. (The Dictionary of Immunology, Academic Press, 4th edition, 1995, p.58) define epitopes as the region on an antigen molecule to which antibody or the T cell receptor binds specifically wherein the 3-dimensional structure of the protein molecule may be essential for antibody binding. However, the specification fails to disclose sufficient guidance and objective evidence as to the linear and or three-dimensional conformation of the polypeptide fragments which constitute epitopes recognized by the claimed invention. Antibodies bind to structural shapes that may be linear stretches of amino acids, conformational determinants formed by the folding of peptides, carbohydrate moieties, phosphate or lipid residues or a combination thereof. Moreover, as evidenced by Greenspan et al., defining epitopes is not as easy as it seems (Nature Biotechnology 7:936-937 (1999). Even when the epitope is defined, in terms of the spatial organization of residues making contact with ligand, then a structural characterization of the molecular interface for binding is necessary to define the boundaries of the epitope (page 937, 2nd column).

Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of

material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

The inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe immunogenic composition comprising that product.

Thus, the instant specification may provide an adequate written description of an isolated recombinant polypeptide, an isolated recombinant fusion protein, immunogenic composition comprising an immunogenic fragment of at least 15 or 20 contiguous amino acids of SEQ ID NO:2, per Lilly by structurally describing a representative number of an isolated recombinant polypeptide, an isolated recombinant fusion protein, immunogenic composition comprising an immunogenic fragment of at least 15 or 20 contiguous amino acids of SEQ ID NO:2, "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe an isolated recombinant polypeptide, an isolated recombinant fusion protein, immunogenic composition comprising an immunogenic fragment of at least 15 or 20 contiguous amino acids of SEQ ID NO:2, in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of any an isolated recombinant polypeptide, an isolated recombinant fusion protein, immunogenic composition comprising an immunogenic fragment of at least 15 or 20 contiguous amino acids of SEQ ID NO:2, nor does the specification provide any partial structure of an isolated recombinant polypeptide, an isolated recombinant fusion protein, immunogenic composition comprising an immunogenic fragment of at least 15 or 20 contiguous amino acids of SEQ ID NO:2, nor any physical or chemical characteristics an isolated recombinant polypeptide, an isolated

recombinant fusion protein, immunogenic composition comprising an immunogenic fragment of at least 15 or 20 contiguous amino acids of SEQ ID NO:2, nor any functional characteristics coupled with a known or disclosed correlation between structure and function. Although the specification discloses a single isolated recombinant polypeptide comprising the amino acid sequence SEQ ID NO:2 this does not provide a description of an isolated recombinant polypeptide comprising an immunogenic fragment of at least 15 or 20 contiguous amino acids of SEQ ID NO:2 that would satisfy the standard set out in Enzo.

The specification also fails to describe an isolated recombinant polypeptide comprising an immunogenic fragment of at least 15 or 20 contiguous amino acids of SEQ ID NO:2 by the test set out in Lilly. The specification describes only a single isolated polypeptide comprising the amino acid sequence SEQ ID NO:2. Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of an isolated recombinant polypeptide comprising an immunogenic fragment of at least 15 or 20 contiguous amino acids of SEQ ID NO:2 that is required to practice the claimed invention. Since the specification fails to adequately describe the product to which the claimed isolated recombinant polypeptide comprising an immunogenic fragment of at least 15 or 20 contiguous amino acids of SEQ ID NO:2, it also fails to adequately describe composition comprising said recombinant polypeptide comprising an immunogenic fragment of at least 15 or 20 contiguous amino acids of SEQ ID NO:2.

Claims 25, 29, 31, 35, 40, 41, 43 , 50, 51 and 57-59 do not comply with 35 USC 112, first paragraph because it is not supported by an adequate written description in the specification. Thus , these claims are also not adequately supported by an adequate written description.

6. Claims 25, 29, 31, 35, 40, 41, 43 , 50, 51 and 57-59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated recombinant polypeptide comprising the amino acid sequence SEQ ID NO: 2, a fusion protein comprising the amino acid sequence SEQ.ID.NO:2, an immunogenic composition comprising the amino acid sequence SEQ.ID.NO: 2 and a method of inducing an antibody response in a mammal comprising administering to the mammal the amino acid sequence SEQ ID NO: 2 does not reasonably provide enablement for an isolated recombinant polypeptide, fusion protein , immunogenic composition and a method of inducing an immune response comprising an immunogenic fragment of at least 15 or 20 contiguous amino acids of SEQ.ID.NO: 2(the examiner is considering these as variants), wherein the immunogenic fragment is capable, when administered to a subject as a conjugate with a suitable carrier which can include an adjuvant, of inducing an antibody response that recognizes the polypeptide SEQ ID NO:2, The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant claims are evaluated for scope of enablement based on the Wands analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731,8 USPQ2d 1400 (Fed.Circ.1988) as follows:

(1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The specification teaches that Neisseria meningitidis (meningococcus) is a Gram-negative bacterium frequently isolated from the human upper respiratory tract. It occasionally causes invasive bacterial diseases such as bacteremia and meningitis. The BASB082 gene of *N. meningitidis* strain ATCC 13090 is shown in SEQ ID NO:I. The translation of the BASB082 polynucleotide sequence, shown in SEQ ID NO:2 (p. 5), shows significant similarity to Pseudomonas aeruginosa PhuP, an outer membrane hemin receptor. The BASB082 polypeptide contains a leader signal sequence, as predicted by the program Spscan of the GCG software package. The predicted signal sequence would be cleaved after residue 24. BASB082 is predicted to be an outer membrane protein involved iron uptake. (pages 1-2).The specification hypothesizes that the claimed polypeptide induces antibodies and would be useful in inhibiting the spread infection . The instant inventors believe that the invention relates to methods for using such polypeptides and polynucleotides, including prevention and treatment of microbial diseases, amongst others, diagnostic assays for detecting diseases associated with microbial infections and conditions associated with such infections, such as assays for detecting expression or activity of BASB082, polynucleotides or polypeptides.

One cannot extrapolate the teaching of the specification to the scope of the claims because the claims as written are drawn to undefined polypeptides which comprise at least 15 or 20 contiguous amino acids of SEQ ID NO:2, wherein the three dimensional structure of the amino acids comprised within the polypeptides are unknown and neither the specification nor the art of record define which amino acid residues of SEQ ID NO:2 are critical for raising of an immune response, i.e. antibodies that are specific for SEQ ID NO:2. As drawn to antibodies, Bowie et al (Science, 1990, 257:1306-1310), teaches that an amino acid sequence encodes a message that determines the shape of a protein and determines the ability of said protein to fold into unique three-dimensional structures that allows them to function. Bowie further teaches that certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (p. 1306, cols 1 and 2). Clearly, the three dimension structure of a protein is critical to the production of antibodies given the teaching of Herbert et al (The Dictionary of Immunology, Academic Press, 3rd Edition, London, 1985, pages 58-59). Herbert et al who specifically teach that an epitope is the region on an antigen molecule to which antibody specifically binds. B cell epitopes on protein antigens are of variable size comprising up to

about 20 amino acids. Antibodies bind in a more or less exact three dimensional fit with an epitope. This may be formed from residues on different regions of a protein antigen molecule which, in the native state, are closely apposed due to protein folding. Thus the three-dimensional structure of the protein molecule may be essential for antibody binding. (p. 58). However, neither the specification nor the art of record provide teachings that provide information about the residues critical for epitopes required for the establishment of an immune response that will produce antibodies that recognize full-length polypeptide, SEQ.ID.NO:2. This information appears to be critical because the art recognizes (see Bowie above) that it is the protein sequence that determines the three dimensional shape of a protein and Herbert et al specifically state that antibodies bind in a more or less exact three dimensional fit and suggests that the three-dimensional structure of the protein molecule may be essential for antibody binding. Thus, in the absence of guidance in the specification,one could not determine how to make the claimed invention or predict that any particular linear peptide would function as claimed with a reasonable expectation of success. Neither the art nor the specification as originally filed provides guidance on how to determine which 15 or 20 amino acids will be capable of, when used as an immunogen, raising antibodies which bind specifically to SEQ ID NO:2. In particular, Roitt et al (Immunology, 1993, Mosby, St. Louis, p 7.7-7.8) teach that although it is possible to produce antibodies to almost any part of an antigen, this does not normally happen in an immune response. It is usually found that only a certain areas of the antigen are particularly antigenic, and that a majority of antibodies bind to these regions. These regions are often at exposed areas on the outside of the antigen, particularly where there are loops of polypeptide that lack a rigid tertiary structure (p.7.7-7.8). This is exemplified by the teaching of Holmes (Exp. Opin.Invest. Drugs, 2001, 10(3):511-519) who teaches that rabbits were immunized with synthetic peptides which in each case generated high anti-peptide specific immunoreactivities, however, none of the antibodies exhibited binding to the full length antigen. The author concludes that 'Presumably, expression of these epitopes in the context of the protein was important and affected the antibody binding ability' (p. 513, col 1). Furthermore, the specification does not take into account the 3 dimensional folding of the native molecule, nor its glycosylation or other post-translational modifications and other characteristics which are of significant importance in an antibody response. Peptides or synthetic antigens cannot effectively substitute for the natural tertiary and quarterary structure of a protein in a physiological situation. Given this teaching, even if the claimed peptides consists of amino acid residues that were 100% identical to portions of SEQ ID NO:2 it would not be possible to determine with any predictability whether the antibodies produced from said peptide would be specific for SEQ ID NO:2 and actually bind to SEQ ID NO: 2 in the absence of guidance from the specification. Although it is obvious that t-cell epitopes and antibody epitopes are not the same, the issues drawn to the lack of guidance in the specification as to critical residues and polypeptide fragments required for T cell binding are relevant to this limitation as well.

Further, there is no teaching in the specification of whether or not the epitopes are linear or comprise 3-dimensional structures. In particular, Greenspan et al (Nature Biotechnology, 1999, 7:936-937)

teaches that defining epitopes is not as easy as it seems. Even when the epitope is defined, in terms of the spatial organization of residues making contact with ligand, then a structural characterization of the molecular interface for binding is necessary to define the boundaries of the epitope (page 937, 2nd column).

As drawn specifically to the polypeptides comprising the 15-20 amino acids of SEQ ID NO:2, Coleman et al. (Research in Immunology, 1994; 145(1): 33-36) teach that single amino acid changes in an antigen can effectively abolish antibody antigen binding. Furthermore, Abaza et al. (Journal of Protein Chemistry, Vol. 11, No. 5, 1992, pages 433-444, see abstract in particular) teach single amino acid substitutions outside the antigenic site on a protein affects antibody binding. Clearly if antibody binding is abolished, it is because of the alteration of the conformation of the epitope to which the antibody binds. Given the clear teaching drawn to conformation alteration with even a single amino acid change, clearly it would be expected that amino acid residues outside of the antigenic epitope, not native to SEQ ID NO:2 would alter the conformation of that epitope in the polypeptide comprising and that it could not be predicted, nor would it be expected that a structurally altered antigenic epitope would produce, for example, antibodies that would bind to SEQ ID NO:2.

The specification provides no guidance or working examples which would provide guidance to one skilled in the art as to which amino acids or polypeptide fragments are critical to the induction of an immune response specific for SEQ ID NO:2 and no evidence has been provided which would allow one of skill in the art to predict which of the broadly claimed polypeptide variants would function as claimed with a reasonable expectation of success. For the above reasons, it appears that undue experimentation would be required to practice the claimed invention.

Thus, it would not be expected that the claimed variant proteins in the absence of further guidance from the specification, would function as claimed or as contemplated given that there is no teaching of residues critical to the claimed function. Further one would not know how to use of said variants that induce response and do not bind to the full length SEQ ID NO:2.

Some of applicant's arguments drawn to previous rejection of the claims under 35 USC 112, first paragraph are relevant to the instant rejection.

Applicant keeps on arguing 10/21/05 and 1/23/07 about the rejection and states that the examiner does not question the immunogenicity of the BASB082 fragments itself. Applicant now provides another set of Exhibits A-J (published journal articles computer program analysis) relating to various short peptides that were used to generate antibodies.

The examiner has replied to applicants arguments in the previous Office action with respect to Exhibits filed in the previous amendment. The examiner has reviewed the exhibits A-D relating to synthetic peptides and E (use of peptide to probe viral antigen for specific epitope) F and G (vaccine related to class 1 membrane protein) H and I (related to protein molecular weight calculator and computer tools) J (accession number for outermembrane for MC 58 strain) understands that short peptides consisting of 6 or

7 or 8 amino acids have been used to raise antibodies and for epitope mapping. The argument has been considered but has not been found persuasive because applicant is partially arguing limitations not recited in the claims as currently constituted since the claims are not drawn to epitope mapping. However, as drawn to raising antibodies, the examiner is not stating that synthetic peptides can not be used for raising antibodies but rather, as set forth above, is stating that the art of epitope identification for induction of immune response for the claimed polypeptides comprising 15-20 amino acids of SEQ ID NO:2 is highly unpredictable in the absence of a teaching of the critical residues required for the induction of the immune response for the reasons clearly set forth above. Further, it is noted that the evidence submitted is not drawn to the claimed fragments of SEQ ID NO:2 , nor is the evidence drawn to polypeptides comprising said fragments or any other polypeptides comprising the 12-20 mers disclosed and thus the evidence presented is not commensurate in scope with the claimed invention.

Remarks

7. Claims 25, 29, 31, 35, 40, 41, 43, 50-51 and 57-59 stand rejected.

Claims 27, 32, 48 and 49 are objected to as being dependent upon a rejected base claim.

Conclusion

8. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Jeffery Siew can be reached on (571) 272-0787. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER

Padma Baskar Ph.D.